MAR 1 2 2001

K010165

510(k) SUMMARY

Submitted By: ETYMOTIC RESEARCH
61 Martin Lane
Elk Grove Village, IL 60007

Telephone: (847)-228-0006

Contact Person: Mr. Steve Iseberg

Date on which Summary was Prepared: February 6, 2001

Name of Device: ERO•SCAN™ OAE Test System

Common Name: Otoacoustic Emissions Test System

Classification: Class II

Description of the Device: The ERO•SCAN OAE Test System consists of a hand-held device and related accessories designed to provide an objective measure of outer hair cell function through the measurement of otoacoustic emissions (OAE's). This device is substantially equivalent to the following predicate devices:

1. Etymotic Research The ERO•SCAN™ Otoacoustic Emissions Test Instrument (K980533).
2. Grason-Stadler IL 088 Otodynamic Analyzer TEOAE testing capability (K890124)

Intended Use: The ERO•SCAN™ OAE Test System is indicated for testing of cochlear function in infants, children and adults by measuring otoacoustic emissions (OAE's). The OAE's are generated by a series of clicks that are directed into the ear canal. Otoacoustic emissions are low level audio-frequency sounds that are produced by the cochlea as part of the normal-hearing process.

Available evidence suggests that otoacoustic emissions are generated by the cochlea's outer hair cells and that the presence of OAE's is an indication that the outer hair cells are viable. Clinical evidence indicates that these emissions normally occur with normal hearing, or at most, mild hearing loss (usually 30-40 dB HL). The majority of hearing-impaired individuals will be identified by a simple OAE test.

Comparison of Similarities and Differences to Predicate Devices:

	Etymotic Research ERO•SCAN™ Otoacoustic Test Instrument, K980533	**Etymotic Research ERO•SCAN™ OAE Test System.**
Indication for Use	Identical for	Both Products
Patient Population	Infants, children, and adults.	Infants, children, and adults.
Type of Display	Liquid Crystal Display (LCD)	Liquid Crystal Display (LCD)
Acoustic Stimulation Level	<90 dB SPL	< 90 dB SPL
Measures Transient Evoked Otoacoustic Emissions (TEOAE's)	No	Yes
Measures Distortion Product Otoacoustic Emissions (DPOAE's)	Yes	Yes (Optional)

	Etymotic Research ERO•SCAN™ Otoacoustic Test Instrument, K980533	**Etymotic Research ERO•SCAN™ OAE Test System.**
Probe Response	+/- 5 dB Over the Range 500 – 6000 Hz (Internal Probe)	+/- 5 dB Over the Range 500 – 6000 Hz (Internal Probe) +/- 3 dB Over the Range 500 – 6000 Hz (External Probe)
Weight of Instrument	Approximately 300 grams	Approximately 300 grams
Power Source	4 x AA Alkaline Only	4 x AA Alkaline Only
Frequency Range	1,500 – 6,000 Hz	500 – 4,000 Hz
Automatic Pass/Fail Test	Yes	Yes
Number of Records Stored	50 ears	50 ears
Battery Operated Printer	Yes	Yes
Provision for Multiple Printouts of Same Test Results	Yes	Yes
Uses Disposable Ear Tips	Yes	Yes
Click Rate	Not Applicable	61/second
Automatic Shut Down	Yes	Yes
Memory Protected by Backup Battery	Yes	Yes
Background Noise Check	Yes	Yes
PC Cable Connectable	Yes	Yes
PC Management Suite	Optional	Optional
Stimulus Intensity Range	40 – 65 dB SPL	70 – 85 dB SPL
Calibration	Performs Self Calibration.	Performs Self Calibration.

The use of click sounds to elicit transient evoked otoacoustic emissions (TEOAE's), is a method used by a predicate device called IL 088 Otodynamic Analyzer submitted by Grason-Stadler, Inc., Littleton, MA 01460 and holds a cleared 510(k) K890124.

What follows is a comparison chart comparing our device to the IL 088 unit:

	IL088 Otodynamic Analyzer. K890124	**Etymotic Research ERO•SCAN™ OAE Test System**
Indication for Use	Identical for	Both Units
Patient Population	Infants, Children and Adults	Infants, Children, and Adults
Type of Display	Computer's CRT Monitor	Built-in Liquid Crystal Display (LCD)
Intensity	90 dB SPL (50 dB SL) Peak	83 dB SPL Peak Equivalent
Measures Transient Evoked Otoacoustic Emissions (TEOAE's)	Yes	Yes
Measures Distortion Product Otoacoustic Emissions (DPOAE's)	No	Yes (Optional)

	IL088 Otodynamic Analyzer. K890124	Etymotic Research ERO•SCAN™ OAE Test System
Power Source	117 V	4xAA Alkaline Only
Frequency Range	0 to 6,000 Hz	500 to 4,000 Hz
Band Limit Filter	500 to 5,000 Hz	500 to 4,500 Hz
Uses Disposable Ear Tips	Yes	Yes
Click	100 μS	160 μS
Repetition Rate	50 Hz	61 Hz
PC Cable Connectable	Yes	Yes
Reference Cavity for Calibration	Yes	Not Required
Analysis Window	2.5 to 20 mS post Stimulus	4.5 to 12 mS Post Stimulus
Number of Responses	260 (Selectable in Steps of 10)	240
Rejection Threshold	23.7 dB to 54.9 dB	20 to 40 dB SPL in Each Analysis Band
Recommended Computer Specifications	IBM-PC- Compatible with at least 10 Mb Hard Disk, 640 K RAM, and an EGA Color Monitor	None Required.

Safety and Effectiveness: The maximum sound pressure level output of our instrument remains well below 90 dB SPL throughout the audible range of 20 Hz to 20kHz. This level is well within OSHA permissible limits of 90 dBA for 8 hours.

The ERO•Scan OAE Test Instrument also meets the general safety requirements of the following voluntary standards: EN 6100-4-2: 1998 (Eectrostatic Discharge Test) and EN 61000-4-3: 1988 Radiated Susceptibility test.

The performance of the ERO•SCAN™ OAE Test System was found to be very similar with regard to the measurement of transient evoked otoacoustic emissions (TEOAE's) to those measured by the IL 088 System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 2 2001

Mr. Steve Iseberg
Manager of Instrumentation Products
ETYMŌTIC RESEARCH, Inc.
61 Martin Lane
Elk Grove Village, IL 60007

Re: K010165
Trade Name: ERO•SCAN™ OAE Test System
Regulatory Class: II
Product Code: 77 EWO
Dated: January 17, 2001
Received: January 18, 2001

Dear Mr. Iseberg:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K010165

510(k) Number (if known):_____

Device Name: ERO•SCAN™ OAE Test System

Indications For Use:

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Available evidence suggests that otoacoustic emissions are generated by the cochlea's outer hair cells and that the presence of OAE's is an indication that the outer hair cells are viable. Clinical evidence indicates that these emissions normally occur with normal hearing, or at most, mild hearing loss (usually 30-40 dB HL). The majority of hearing-impaired individuals will be identified by a simple OAE test.

James K. Koch, M.D.

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K010165

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

EV II

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